REMARKS

By the foregoing amendments, claims 77-87 are pending in this application. Claims 1-76 and 88-113 have been canceled without prejudice or disclaimer. Claims 80-82 have been withdrawn as not elected in response restriction requirement mailed November 14, 2007. Applicants reserve the right to pursue this subject matter in one or more divisional applications.

Independent claim 77 has been amended to recite the feature of now-canceled claim 88, namely an increased level of expression that is at least 150% relative to the control. Dependent claims 84 and 87 have been amended to recite an expression product that is an RNA (claim 84), or a polypeptide encoded by the RNA (claim 87), comprising a nucleotide sequence corresponding to the elected DNA sequence of SEQ ID NO:26.

The claim amendments add no new matter.

Information Disclosure Statements

Applicants thank the Examiner for considering the references cited in the Information Disclosure Statements filed February 11, 2008 and November 8, 2007. Applicants will resubmit the Information Disclosure Statement filed September 17, 2003 with the titles of the non-patent literature documents included.

The Rejection under 35 U.S.C. § 112, ¶ 2 (Indefiniteness)

The office action asserts that the pending claims are indefinite, because it is not clear from the claim language which expression products (RNA or polypeptide) can be assayed from which patient samples (prostate or blood). Applicants respectfully traverse.

The definiteness of language used in a claim "must be analyzed –not in a vacuum, but always in light of the teachings of the prior art and of **the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art**." *In*

re Moore, 439 F.2d 1232, 1235, 58 C.C.P.A. 1042, 1046-47 (1971) (emphasis added). The importance of the specification in determining whether the claims are definite also was emphasized in *In re Cohn*, 438 F.2d 989, 993, 58 C.C.P.A. 996, 1001 (C.C.P.A. 1971): "No claim may be read apart from and independent of the supporting disclosure on which it is based."

In this case, one skilled in the art would readily understand the specification as being directed to expression products of viruses in prostate cells. Both RNA and polypeptide expression products of these viruses can therefore be assayed in prostate cells, while polypeptide expression products can be assayed in blood cells. This is also made clear in the specification. See, for example, page 24, line 23 to page 25, line 9. One of ordinary skill, upon reading the specification, would therefore easily comprehend the meaning of expression products that can be assayed in a patient prostate or blood sample. The claim language ". . . assaying, in a patient prostate or blood sample, an expression product. . ." is definite.

The Office Action also considers the word "increased" as indefinite. To advance prosecution, an increased expression level of at least 150% relative to a control sample is now recited in claim 77 as requested in the Office Action.

Please withdraw the rejection under 35 U.S.C. 112 ¶ 2.

The Rejection under 35 U.S.C. § 112, ¶ 1 (Enablement)

The pending claims have been rejected as lacking enablement under 35 U.S.C. § 112 ¶ 1. Applicants respectfully traverse.

To advance prosecution, the currently pending claims 77-79 and 85 are all directed to the particular HML-2 retrovirus, namely HERV-K(CH). Page 6 of the Office Action acknowledges that this subject matter is enabled: ". . .the specification, while being enabling for assaying HERV-K(CH) expression product. . .". See also the second paragraph of page 7 of the Office

Action.

Please withdraw the rejection under 35 U.S.C. § 112, ¶ 1.

CONCLUSION

In view of the above amendments and remarks, all pending claims of this application are believed to be in condition for allowance. A written indication of the same is respectfully requested. This response is believed to completely address all of the substantive issues raised in the Office Action mailed May 28, 2008.

Please continue to direct all correspondence in this application to Novartis Vaccines and Diagnostics, Inc. (formerly Chiron Corporation), at the address provided for Customer No. 27476.

Respectfully submitted,
BANNER & WITCOFF, LTD.

Date: November 20, 2008

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